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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,514	07/30/2003	Bret R. Shoberg	P-11234.00	7898
27581	7590	02/14/2007	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/630,514

Applicant(s)

SHOBERG ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-43 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-43 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1, 3, 11, 20, 21, 23, 24, 32, 41, 42 and 57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower et al. (US 5,476,497, hereinafter "Mower").

5. In regards to claim 1, Mower discloses an elastomeric multi-lumen tube including a lumen that forms a substantially elliptical cross-section (Fig. 3) and a minor axis having a first length and a second length longer than the first length (Figs. 2 and 3); and an elongated conductor (16 and 18) extending within the lumen, having a substantially circular cross-section greater than the first length (col. 3, lines 5-10). Please note that the diameter ranges given by Mower disclose an embodiment wherein the outer diameter of the conductor is greater than the minor axis length of the elliptical lead body, inherently contacting the inner surface to maintain the lumen in a deformed state and reducing the length of the major axis (as in Fig. 3). Additionally, Figure 3 shows multiple lumens for the tube when placed in this configuration because the empty areas bounded by 26 and 10 can be considered "lumens"; or, when the inner conductor contacts the inner walls of the lumen, this will necessarily create multiple lumens within the claimed "lumen". Alternatively, Mower discloses the essential features of the claimed invention except for a multi-lumen elastomeric tube. It is well known in the art to provide multi-lumen elastomeric catheters to allow the application of multiple independent electrodes to the heart or other areas to stimulate or sense discrete areas. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mower's device with multiple lumens to allow the

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application of multiple independent electrodes to the heart or other areas to stimulate or sense discrete areas.

6. In regards to claim 3, Mower further discloses the conductor has an outer sheath (20), which necessarily has a diameter longer than the minor axis because it has a diameter larger than the conductor.

7. In regards to claim 11, Mower discloses that the inner surface of the lumen comprises a flattened portion (e.g. the top and bottom portions of Figure 1 are generally flattened).

8. In regards to claims 20, 21, 41, and 42, the tube is formed of silicone or polyurethane (col. 2, line 59).

9. In regards to claim 23 and 32, a circular conductor contacting the walls of the oval-shaped sheath will inherently create two substantially crescent-shaped spaces.

10. In regards to claim 24, the conductor includes a sheath (20 and 22).

11. Claims 4- 9, 22, 25-30, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower. Mower discloses the essential features of the claimed invention except for a sheath comprising a fluoropolymer, a lubricious lumen inner surface, a coiled conductor including a lumen containing another conductor, an extendable and retractable electrode, a cable conductor, or a tube comprising silicone and polyurethane. It is well known in the art to provide a lead with a sheath comprising a fluoropolymer (such as PTFE) to provide a lead that is highly durable in the human body; a lubricious lumen inner surface to allow conductors or other devices to be

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advanced easily to various parts of the body without getting stuck in the guide sheath; a coiled conductor including a lumen containing another conductor to provide a bendable conductor that can provide stimulation or sensing to several electrodes; an extendable and retractable electrode to allow an electrode to be attached to body tissue without snagging on unwanted locations during insertion; a cable conductor to provide a conductor that is stronger and more pliant than a solid conductor; and a tube comprising silicone and polyurethane to provide a strong, yet highly bendable tube. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mower's invention with a sheath comprising a fluoropolymer (such as PTFE) to provide a lead that is highly durable in the human body; a lubricious lumen inner surface to allow conductors or other devices to be advanced easily to various parts of the body without getting stuck in the guide sheath; a coiled conductor including a lumen containing another conductor to provide a bendable conductor that can provide stimulation or sensing to several electrodes; an extendable and retractable electrode to allow an electrode to be attached to body tissue without snagging on unwanted locations during insertion; a cable conductor to provide a conductor that is stronger and more pliant than a solid conductor; and a tube comprising silicone and polyurethane to provide a strong, yet highly bendable tube.

12. Claims 10, 18, 31, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower in view of Williams et al. (US 5,871,530, hereinafter "Williams"). Mower discloses the essential features of the claimed invention except for

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a lumen with an asymmetrical cross-section or an overlay sheath about the multi-lumen tube. Williams teaches of providing a lumen with an asymmetrical cross-section to loosely hold a conductor, thus providing ease of insertion and removal (col. 8, line 62); and an overlay sheath (30) about the multi-lumen tube to provide a stiff conduit for delivery of the lead. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mower's lead with an asymmetrical cross-section to loosely hold a conductor, thus providing ease of insertion and removal; and an overlay sheath about the multi-lumen tube to provide a stiff conduit for delivery of the lead.

13. Claims 12-17, 19, 33-38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower in view of Shoberg et al. (US 5,584,873, hereinafter "Shoberg"). Mower discloses the essential features of the claimed invention except for a minimum wall thickness between approximately 0.002 inch and approximately 0.008 inch; a plurality of lumens offset from the center point of the tube; a plurality of lumens comprising three lumens with substantially circular cross-sections and having conductors therein; or an electrode with an outer diameter approximately equal to an overlay sheath. Shoberg teaches of providing a multi-lumen lead with a minimum wall thickness of approximately 0.008 inch (col. 4, line 9) to provide a lead that is both small to allow passage through small vessels and insulated enough to avoid short circuits; a plurality of lumens offset from the center point of the tube to provide the ability of the lead to carry many conductors to various discrete parts of the body; a plurality of lumens

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comprising three lumens with substantially circular cross-sections and having conductors therein (Fig. 4) to carry multiple conductors that provide sensing and stimulating capability to several chambers or areas of the heart; and an electrode (14) with an outer diameter approximately equal to an overlay sheath (12) to provide an isodiametric lead that will avoid snagging. Alternatively, it is well known in the art to minimize the diameter of leads to allow passage through small vessels and minimize trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mower and Williams' invention with a minimum wall thickness of approximately 0.008 inch to provide a lead that is both small to allow passage through small vessels and insulated enough to avoid short circuits; a plurality of lumens offset from the center point of the tube to provide the ability of the lead to carry many conductors to various discrete parts of the body; a plurality of lumens comprising three lumens with substantially circular cross-sections and having conductors therein to carry multiple conductors that provide sensing and stimulating capability to several chambers or areas of the heart; and an electrode with an outer diameter approximately equal to an overlay sheath to provide an isodiametric lead that will avoid snagging.

Response to Arguments

14. Applicant's arguments with respect to claims 1 and 3-43 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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2/12/07

George E. Egan
Primary
2/12/7